UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

JAMES PETER,

Plaintiff,

v.

Case No. 07-13298

STRYKER ORTHOPAEDICS, INC., THE STRYKER CORPORATION, STRYKER BIOTECH, L.L.C., HOWMEDICA OSTEONICS CORP., STRYKER TECHNOLOGIES CORP.,

Honorable Patrick J. Duggan

Defendants.
_____/

OPINION AND ORDER

At a session of said Court, held in the U.S. District Courthouse, Eastern District of Michigan, on January 29, 2009.

PRESENT: THE HONORABLE PATRICK J. DUGGAN
U.S. DISTRICT COURT JUDGE

On July 3, 2007, Plaintiff James Peter filed this lawsuit in Wayne County Circuit Court, against Defendants Stryker Orthopaedics, Inc., The Stryker Corporation, Stryker Biotech, L.L.C., Howmedica Osteonics Corp., and Stryker Technologies Corp. Plaintiff alleged three claims: statutory products liability, breach of warranty, and a violation of the Michigan Consumer Protection Act ("MCPA"), Mich. Comp. Laws § 445.903(y), stemming from injuries he allegedly suffered from a prosthetic knee designed, manufactured, and sold by defendants. Presently before the Court is Howmedica

Osteonics Corp.'s ("Howmedica") Motion for Summary Judgment. For the reasons stated below, Howmedica's motion is granted.

I. Facts and Procedural Background

After nearly two decades of right knee problems, Plaintiff underwent total knee replacement surgery on June 12, 2000. At that time, Plaintiff's surgeon implanted a Howmedica Duracon Total Knee system, a medical device subject to regulation by the Food and Drug Administration ("FDA"). The prosthesis was packaged with warnings stating that patients should limit their activities, avoid placing the joint under unreasonable stress, and that infection could cause prosthesis to fail. After the surgery, Plaintiff enjoyed a year of improved mobility and decreased pain.

Nonetheless, Plaintiff's medical records reveal that by October 2001 he was once again experiencing pain and swelling in his right knee. Despite various treatments, Plaintiff continued to have problems that his doctors attributed to chronic infection. By February 2002, Plaintiff had to be hospitalized for an infection in the knee. An x-ray in August 2002 revealed bone loss directly under the prosthesis. Plaintiff's condition continued to deteriorate despite regular treatments with antibiotics and several arthroscopic surgeries. By December 2003, Plaintiff was in constant pain.

In mid-2004, Plaintiff's doctor began to speculate that the tibial component of Plaintiff's prosthetic knee might have loosened, contributing to the pain and swelling. In an attempt to remedy the suspected loosening, Plaintiff underwent revision surgery on July 5, 2004. At that time, Plaintiff's prosthetic knee was removed and the surgeon discovered that the tibial base plate component of the prosthesis had a "definite fracture."

Below the fractured plate, Plaintiff's bone had deteriorated and become soft or mushy requiring that it be shaved down four to five millimeters before a new prosthesis could be implanted. Under normal conditions, that bone provides support for the tibial base plate in the prosthetic knee.

Plaintiff has continued to experience knee problems since the July 2004 surgery. In November 2005, the second prosthesis was removed and Plaintiff's doctors inserted an antibiotic spacer in its place. In September 2006, a third prosthetic knee was implanted but Plaintiff continues to suffer from pain in the joint.

Plaintiff brought the present suit in state court on July 3, 2007, alleging that some of the prosthetic components of his Howmedica Duracon Total Knee system were defective and failed prematurely after implantation. On August 8, 2007, defendants removed Plaintiff's complaint to this Court pursuant to 28 U.S.C. §1441. On September 13, 2007, the parties stipulated to the dismissal of all of the defendants except for Howmedica. Howmedica previously filed a motion for partial summary judgment which this Court granted in part on October 6, 2008. Pursuant to that order, Plaintiff's MCPA claim was dismissed.

On November 17, 2008, Howmedica filed motions requesting that this Court enter an order striking Plaintiff's expert report, excluding Plaintiff's expert testimony, and extending the dates contained in a prior scheduling order. The Court scheduled a hearing on the motion for December 4, 2008. Plaintiff's counsel failed to file a response to the motions and failed to appear for the hearing. The next day, the Court entered an order granting Plaintiff's motions, extending the deadline for dispositive motions to December

23, 2008, and ordering that Plaintiff's counsel pay sanctions in the amount of $2500 to Howmedica by December 18, 2008, to avoid dismissal of the case. Plaintiff's counsel has yet to pay the sanctions.

Nonetheless, Howmedica filed the present motion for summary judgment on December 22, 2008. Once again, Plaintiff's counsel failed to respond to the motion.

II. Standard for Summary Judgment

Summary judgment is appropriate only when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c). The central inquiry is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52, 106 S. Ct. 2505, 2512 (1986). After adequate time for discovery and upon motion, Rule 56(c) mandates summary judgment against a party who fails to establish the existence of an element essential to that party's case and on which that party bears the burden of proof at trial. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S. Ct. 2548, 2552 (1986).

The movant has an initial burden of showing "the absence of a genuine issue of material fact." *Id.* at 323, 106 S. Ct. at 2553. Once the movant meets this burden, the non-movant must come forward with specific facts showing that there is a genuine issue for trial. *Matsushita Electric Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S. Ct. 1348, 1356 (1986). "When a motion for summary judgment is properly made and supported, an opposing party may not rely merely on allegations or denials in its own pleading . . . ." Fed. R. Civ. P. 56(e)(2). To demonstrate a genuine issue, the non-movant

must present sufficient evidence upon which a jury could reasonably find for the non-movant; a "scintilla of evidence" is insufficient. *Liberty Lobby*, 477 U.S. at 252, 106 S. Ct. at 2512.

III. Presumption of No Liability

Howmedica argues that it is entitled to summary judgment on Plaintiff's remaining claims for products liability and breach of implied warranty because Plaintiff cannot overcome the presumption of no liability provided by Michigan statutory law. Michigan Compiled Laws section 600.2946(4) provides:

> In a product liability action brought against a manufacturer or seller for harm allegedly caused by a product, there is a rebuttable presumption that the manufacturer or seller is not liable if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm was in compliance with standards relevant to the event causing the death or injury set forth in a federal or state statute or was approved by, or was in compliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state agency responsible for reviewing the safety of the product.

This presumption applies equally to products liability and breach of implied warranty actions. *See* Mich. Comp. Laws § 600.2945(h)-(I) (defining "product liability action"); *see also Mutual Ins. Co. of Am. v. Royal Appliance Mfg. Co.*, 112 Fed. Appx. 386, 389 (6th Cir. 2004).

The prosthetic knee at issue in this case is a medical device subject to comprehensive federal regulations promulgated by the FDA regarding its design and manufacture. *See* 21 C.F.R. § 820 *et seq.* In seeking clearance to market the prosthesis, Howmedica submitted a technical report to the FDA regarding the safety and

effectiveness of the tibial base plate as compared to other similar devices. Specifically included in the technical report were test results regarding the fatigue endurance load of the tibial base plate in a situation in which partial support for the tibial tray had been lost. The tibial base plate's performance was similar to other clinically successful total knee tibial components. (*See* Def.'s Mot. Ex. 1.) The FDA gave Howmedica clearance to market the prosthesis in 1994.

After obtaining clearance, Howmedica began producing the prosthetic knee under comprehensive procedures, specifications, and protocols designed to meet the requirements of the FDA's "Quality System Regulations." *See* 21 C.F.R. § 820.1. These regulations "are intended to ensure that finished devices will be safe and effective . . . ." *Id.* Howmedica records indicate that the product lot that included Plaintiff's prosthesis was produced in accord with the relevant procedures, specifications, and protocols. (Def.'s Mot. Ex. 1, 9.) Based on this evidence, the Court concludes that Howmedica is entitled to the presumption of no liability provided by Michigan law.

To avoid summary judgment, Plaintiff must "offer admissible evidence to rebut the presumption" of no liability. *Lesho v. Textron, Inc.*, 408 F. Supp. 2d 329, 334 (2005); *see also Michal v. PDK Labs*, No. 234943, 2003 WL 2216048, at *5. Plaintiff has failed to submit any evidence. Therefore, Howmedica is entitled to summary judgment on Plaintiff's remaining claims.[1]

[1]Howmedica also argues that Plaintiff has failed to establish a genuine issue of material fact regarding whether the prosthetic knee was defectively designed or manufactured or whether the prosthetic knee was the proximate cause of his injuries. Plaintiff's failure to submit evidence in response to Howmedica's motion for summary judgment is also relevant to these issues. The

Accordingly,

IT IS ORDERED that Howmedica's motion for summary judgment is **GRANTED**.

A judgment consistent with this order shall issue.

s/PATRICK J. DUGGAN
UNITED STATES DISTRICT JUDGE

Copies to:
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Court need not specifically address these issues, however, because the rebuttable presumption of no liability is dispositive in this case.